Unproven Stem Cell "Treatments" Drawing Attention from Regulators, Legislators

Many of us in the scientific and clinical communities have long been angered and outraged by clinics operating around the world that market unproven stem cell "treatments" directly to patients, and the ISSCR has spoken out about this issue for many years.

It is particularly distressing that patients, hopeful for relief or a cure for an intractable disease or injury, can end up paying clinics many hundreds of dollars for unproven "treatments," often unaware that the products are not approved for use as advertised, have not been scientifically tested to know if they work, and are possibly risky. This includes autologous use, which can also carry with it tremendous risk, even death.

Providing false hope to patients, while putting them unknowingly at risk, is grossly irresponsible, and inconsistent with medical and ethical standards. Yet thousands of these clinics continue to operate in jurisdictions around the world.

New Regulatory Efforts

It appears as if that may be changing. Due to the global efforts of scientists and clinicians, including groups such as the ISSCR, we are seeing signs that regulatory and legislative efforts are being implemented to clamp down on clinics peddling risky stem cell treatments, and help patients by providing clear information about whether advertised stem cell products are safe and proven to work. The days of clinics operating without regulation and misleading patients are, we hope, numbered.

In the U.S.

In recent months, the U.S., the Food and Drug Administration (FDA) announced enforcement actions against two clinics; it seized unapproved products from StemImmune Inc. of San Diego, California, and issuing a warning letter to the U.S. Stem Cell Clinic of Sunrise, Florida. Both were providing "unapproved and potentially dangerous" stem cell interventions that were putting patients at risk. In the announcement, the FDA commissioner stated that the agency "will take a firm stance against those that prey on the medical promise of regenerative cell therapies to market treatments potentially unsafe or unproven so-called cures."

As part of the FDA effort, the agency also announced an upcoming release of both new regulatory and enforcement measures meant to more clearly define stem cell treatments that require agency oversight, and more effective pursuit of clinics that don't comply with legal and regulatory guidelines.

The FDA step is a big one, as other jurisdictions often look to the agency for guidance on regulatory frameworks and enforcement.

Outside the U.S.

In Australia, the government has announced it will change regulations regarding the use of autologous stem cell interventions, which previously fell outside the regulatory regime. Autologous human cell and tissue products are those that are removed from a patient, and then re-applied to that same patient. Recognizing some of these products can be risky for patients, based on several reports, the government's effort is meant to bring those products into the regulatory regime.

Health Canada has also communicated to reporters that it will be reaching out to private Canadian clinics that sell unproven stem cell interventions—many of them also autologous. The agency intends to

verify that the clinics are in compliance with the Food and Drugs Act in Canada. [Health Canada has only approved one stem cell treatment for clinical use].

India also appears to be tightening up oversight of stem cell-based interventions, with the release of National Guidelines for Stem Cell Research that come down strongly against unproven uses of stem cells. They admonish that "…every use of stem cells in patients outside an approved clinical trial is unethical and shall be considered as malpractice." Authored by the Indian Council of Medical Research, along with the Department of Health Research and Department of Biotechnology, the guidelines state that "…stem cells are still not a part of standard of care; hence there can be no guidelines for therapy until efficacy is proven."

New Legislation in California

Actions to reign in the clinics providing unproven stem cell interventions have not been limited to national regulatory agencies. A measure signed into law 3 October in California, U.S., requires clinics to inform patients if they are using stem cell interventions that have not been approved by the FDA. Senate Bill 512 mandates that clinics post a notice in their offices, and provide a handout to each patient, stating that the procedure has not been approved for clinical use. California's effort provides patients with information to make more informed decisions about their healthcare.

Ensuring Stem Cell Products are Safe

As potential therapies are developed in the lab, and then translated into products for medical use, they require robust independent review and testing to ensure they are safe and effective. The ISSCR's Guidelines for Stem Cell Research and Clinical Translation provides recommendations for this process, emphasizing the critical need for scientific evidence from clinical trials before medicines can be approved for patients.

With a commitment to the notion that patient health is paramount, the ISSCR advocates that regulators and policy makers around the globe be vigilant in helping ensure proper regulation, oversight, and transparency regarding the sale and use of stem cell treatments.